

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5, 8-24, 27, 28, 30-32, drawn to an apparatus for detecting substances or analytes from the analysis of one or several samples

Group II, claim(s) 33-43, drawn to a method for detecting substances or analytes from the analysis of one or more samples.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I and II appears to be that they both relate to an apparatus that includes a homogenizing system, a reaction chamber, and a sensor system for detecting an analyte.

However, such an apparatus is disclosed by Lawrence et al., 20020197631. Lawrence disclose an apparatus that includes a porous barrier for homogenizing biological samples such as tissues. The homogenized sample can be further processed directly within the device without need for removal. The initial homogenization/processing can be further combined with standard extraction or analytical procedures. Paragraph 0046.

The device can contain additional compartments separated by non-porous, penetrable barriers. The compartments can, for example, contain reagents suitable for purification, reaction, or analysis of the sample. The surface of one or more compartments can be coated with material, making the surface inert to biomolecules; or the surface can be derivatized (i.e. covalently attached or ionically bonded) with biomolecules or molecules capable of interacting with biomolecules. The sample can be forced into the additional compartments in a sequential manner using pressure from

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the pressure modulation apparatus. For example, pressure can be continually increased, forcing the sample into consecutive adjacent compartments. Cycling of the pressure causes the sample and reagents in the subsequent chambers to become sufficiently mixed together. Each consecutive compartment can expose the sample to an additional step of processing. The number of consecutive compartments required in each device varies depending on the degree of processing desired for each individual sample. Paragraph 0049.

One or more of the compartments is equipped with a device (e.g., a photometer) that enables analysis and/or detection of the sample. Forms of analysis include but are not limited to measurement of temperature, pressure, radiation, absorbance, fluorescence, or turbidity. Paragraph 0070.

Therefore, the technical feature linking the inventions of groups I and II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be an apparatus comprising a homogenizer module, a sample processing module, a reaction module, a reagent and solution management module storing and dispensing reagents and solutions, a data reading module through which reactions are detected, and an overall controller supervising the process.

The special technical feature of Group II is considered to be a method comprising the steps of homogenizing with a homogenizing system, adding reagents to modify the sample, filtering the sample, injecting the sample in a reaction chamber, allowing the sample to react with a biosensor, washing the non-reacted sample excess, and detecting the sample retained in the biosensor.

Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Thurs. 9-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/  
Primary Examiner, Art Unit 1641